REMARKS

The pending Office Action addresses and rejects claims 1 and 3-29. Reconsideration is respectfully requested in view of the following remarks.

Rejections Pursuant to 35 U.S.C. §103

Claims 1, 3-8, and 17-29

The Examiner rejects claims 1, 3-8, and 17-29 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,494,209 of Kulick in view of U.S. Patent No. 7,021,312 of Cannon and U.S. Patent No. 4,270,531 of Blachy. In particular, the Examiner argues that Kulick discloses the claimed invention except for a mouthpiece that seals the patient's mouth and a nasal mask adapted to deliver gases through a patient's nasal passageway. The Examiner relies on Blachy to teach a mouthpiece that seals the patient's mouth, arguing that it would have been obvious "to modify the mouthpiece (1) of Kulick with the front surface (46) and gum-engaging surface (34), as taught by Blachy, because the front surface prevent[s] atmospheric air from penetrating and affecting the airflow." The Examiner relies on Cannon to teach a nasal mask, arguing that it would have been obvious "to modify the invention of Kulick to incorporate a nasal mask for the delivery of gases through the patient's nasal passageway as such is well known in the art as taught by Cannon." Applicant disagrees.

Independent claim 1 is directed to a system for maintaining an open airway that includes a mouthpiece that is adapted to substantially seal an oral cavity within a patient's mouth. The mouthpiece is further adapted to be coupled to a negative pressure generator that is effective to create a negative pressure within the oral cavity to prevent the soft tissues of the upper airway from collapsing. Independent claim 17 recites a method for maintaining an open airway by forming a substantially sealed oral cavity within a patient's mouth and creating a negative pressure therein to prevent the soft tissues of the upper airway from collapsing.

The Examiner suggests that one of ordinary skill in the art would modify the mouthpiece (1) of Kulick to incorporate the front surface (46) and the gum-engaging surface (34) of Blachy because doing so would prevent atmospheric air from penetrating and affecting the airflow. It is for exactly

that reason why one of ordinary skill in the art would *not* make such modifications, i.e., because it would prevent atmospheric air from penetrating the mouthpiece (1) of Kulick. Kulick provides the breathing channels (4) as part of the mouthpiece (1) in order to "permit oral breathing at any time when the device is in use." (Col. 3, lines 52-53.) Incorporating the front surface (46) and the gum-engaging surface (34) of Blachy into the mouthpiece (1) of Kulick would block the breathing channels (4). Such a modification would not only render the device inoperative for its intended purpose, but it is specifically contrary to the teachings of Kulick. In particular, as explained at Col. 2, lines 25-30 of Kulick, "[t]he present invention differs from the Samelson device by creating a suction with an external source and permitting the user to breathe through the mouth. This is important because even when there is normal nasal anatomy, the nasal passage may become congested, especially when infection or allergies are present." Kulick thus makes it clear that the breathing channels are an essential feature of the invention, and thus no person having ordinary skill in the art would make the modifications suggested by the Examiner.

Not only are the suggested modifications contrary to the teachings of Kulick, but they would also prevent the mouthpiece from working as designed because they would prevent the tongue from projecting forward into the tongue-receiving cavity. The bite blocks (2) are specifically designed to allow the tongue to project forwardly into the tongue-receiving cavity (19) without getting injured. (*See* Col. 3, lines 57-60.) Incorporating the front surface (46) and the gum-engaging surface (34) of Blachy into the Kulick mouthpiece (1) would block the tongue's path into the cavity (19) because these two surfaces (34, 46) would close off the cavity from the tongue.

Accordingly, because the Examiner's suggested modifications would both render the mouthpiece of Kulick unsatisfactory for its intended purpose, would change the principle of operation of the mouthpiece of Kulick, and is specifically contrary to the teachings of Kulick, no person of ordinary skill in the art would modify Kulick in view of Blacky.

The Examiner also admits that Kulick fails to teach a nasal cannula, and thus relies on Cannon to remedy this deficiency of Kulick. However, a person of ordinary skill in the art would not modify the mouthpiece of Kulick to include the nasal mask (14) of Cannon because Kulick already provides the necessary means for breathing, namely breathing channels (4). As explained above, the breathing channels (4) permit oral breathing at any time when the device is in use, and this is an

essential feature of Kulick. As for the nasal mask (14) of Cannon, the entire design of device (10) is premised on using the nasal mask (14) to assist in breathing through the nose. (*See* Col. 2, lines 54-67.). Thus, the inclusion of a nasal mask (14) of Cannon with the mouthpiece (1) of Kulick in order to provide a means for breathing is extraneous and only done in an attempt to render Applicant's claims obvious. Kulick therefore cannot be modified in view of Cannon.

Accordingly, independent claims 1 and 17, as well as claims 3-8 and 18-29 which depend therefrom, distinguish over Kulick in view of Cannon and Blachy and represent allowable subject matter.

The Examiner also cites U.S. Patent No. 6,012,455 of Goldstein in rejecting dependent claim 6. Claim 6 depends from claim 1, and thus for reasons discussed above pursuant to claim 1, claim 6 distinguishes over Kulick, Blachy, and Cannon. Goldstein does not remedy the deficiencies of Kulick, Blachy, and Cannon as Goldstein is merely cumulative of Cannon.

Claims 9-16

The Examiner rejects independent claim 10 and dependent claims 9 and 11-16 pursuant to 35 U.S.C. §103(a) as being obvious over Kulick in view of Cannon and Blachy and further in view of U.S. Patent No. 6,655,385 of Curti. Similar to independent claim 1, independent claim 10 is directed to a system for maintaining an open airway that includes a mouthpiece that is adapted to substantially seal an oral cavity within a patient's mouth. The mouthpiece is further adapted to be coupled to a negative pressure generator that is effective to create a negative pressure within the oral cavity to prevent the soft tissues of the upper airway from collapsing. As discussed above, Kulick does not teach or even suggest a mouthpiece that forms a substantially sealed oral cavity and neither Cannon nor Blachy can be relied on to remedy the deficiencies of Kulick. Curti likewise does not remedy the deficiencies of Kulick, Cannon, and Blachy because Curti fails to teach such a method or device. Curti is merely directed to a nasal cannula and does not include any type of mouthpiece. Accordingly, independent claim 10, as well as dependent claims 9 and 11-16 because of their dependence from either independent claims 1 or 10, distinguish over Kulick, Cannon, Blachy, and Curti and represent allowable subject matter.

Conclusion

Applicant submits that all pending claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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Pending Claims

1. (Previously Presented) A system for maintaining an open airway, comprising:

a mouthpiece adapted to substantially seal an oral cavity within a patient's mouth and adapted to be coupled to a negative pressure generator that is effective to create a negative pressure within the oral cavity to prevent the patient's soft tissues of the upper airway from collapsing; and

a nasal mask adapted to deliver gases through the patient's nasal passageway.

2. (Cancelled).

3. (Original) The system of claim 1, wherein the mouthpiece is effective to prevent the patient's soft tissues of the upper airway from collapsing without impinging on the tongue.

4. (Original) The system of claim 1, wherein the mouthpiece includes upper and lower portions that conform to an anatomy of the patient's upper and lower dental structures.

5. (Original) The system of claim 1, wherein the mouthpiece includes a hollow elongate member extending therefrom and coupled to a negative pressure generator.

6. (Original) The system of claim 1, wherein the nasal mask is coupled to the mouthpiece.

7. (Original) The system of claim 1, further comprising a negative pressure generator.

8. (Original) The system of claim 1, wherein the nasal mask is coupled to a device selected from the group consisting of a continuous positive airway pressure device, a mechanical ventilation device, and a positive end expiratory pressure device.

9. (Previously Presented) The system of claim 1, wherein the nasal mask includes first and second tubular members extending therethrough and in communication with the patient's nasal passageway, the first tubular member being adapted to deliver gases through the

patient's nasal passageway and the second tubular member being adapted to allow a gas sample to be taken from the nasal passageway.

10. (Previously Presented) A system for maintaining an open airway, comprising:

a mouthpiece adapted to substantially seal an oral cavity within a patient's mouth and including an outlet port positioned during use adjacent the opening of the patient's mouth, the outlet port being adapted to couple to a negative pressure generator to create a negative pressure within the oral cavity; and

a tubular member adapted to be disposed over a patient's nose and to deliver gases to the patient's nasal airway.

11. (Previously Presented) The system of claim 10, wherein the tubular member is coupled to the mouthpiece.

12. (Previously Presented) The system of claim 10, wherein the mouthpiece is effective to prevent the patient's soft tissues of the upper airway from collapsing without impinging on the tongue.

13. (Original) The system of claim 10, further comprising a negative pressure generator.

14. (Original) The system of claim 10, wherein the tubular member comprises a nasal mask that is adapted to form a seal with the patient's nasal airway.

15. (Original) The system of claim 14, wherein the nasal mask is coupled to a device selected from the group consisting of a continuous positive airway pressure device, a mechanical ventilation device, and a positive end expiratory pressure device.

16. (Original) The system of claim 10, further comprising a second tubular member in communication with the patient's nasal passageway for allowing an gas sample to be taken from the nasal passageway.

17. (Previously Presented) A method for maintaining an open airway, comprising:

forming a substantially sealed oral cavity within a patient's mouth;

creating a negative pressure within the substantially sealed oral cavity effective to prevent the patient's soft tissues of the upper airway from collapsing; and

delivering gases through the patient's nasal passageway.

18. (Previously Presented) The method of claim 17, wherein a mouthpiece is used to form the substantially sealed oral cavity.

19. (Previously Presented) The method of claim 18, wherein the mouthpiece is adapted to allow normal swallowing and breathing.

20. (Previously Presented) The method of claim 18, wherein the mouthpiece does not impinge upon the tongue.

21. (Previously Presented) The method of claim 18, wherein the mouthpiece includes upper and lower portions that conform to an anatomy of the patient's upper and lower dental structures.

22. (Previously Presented) The method of claim 21, wherein the upper and lower portions are adapted to maintain the upper and lower dental structures at a fixed distance from one another.

23. (Previously Presented) The method of claim 18, wherein the mouthpiece is adapted to expand the size of the substantially sealed oral cavity in the mouth.

24. (Previously Presented) The method of claim 18, further comprising a hollow elongate member having a first end coupled to the mouthpiece and in communication with the substantially sealed oral cavity, and a second end coupled to the negative pressure generator.

25. (Original) The method of claim 24, wherein the first end of the hollow elongate member is coupled to the mouthpiece adjacent an opening to the patient's mouth.

26. (Previously Presented) The method of claim 18, wherein the mouthpiece includes a sidewall adapted to be positioned over an opening of the patient's mouth, and a positioning member adapted to fit within the mouth to maintain the mouthpiece at a fixed position.

27. (Original) The method of claim 24, wherein the negative pressure generator operates at a pressure in the range of about 0 cm to -60 cm of water.

28. (Original) The method of claim 24, wherein the negative pressure generator removes air from the substantially sealed cavity at a rate that is in the range of about 0 cc/minute to 50 cc/minute.

29. (Previously Presented) The method of claim 17, wherein the negative pressure created within the substantially sealed oral cavity is further effective to remove secretions therefrom.

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